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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,563	08/14/2006	Wayne A Jensen	DI-13-C6-PUS	8347

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HESKA CORPORATION
LEGAL DEPARTMENT
3760 ROCKY MOUNTAIN AVE
LOVELAND, CO 80538

EXAMINER	
CHEU, CHANGHWA J	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
09/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,563	JENSEN ET AL.	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32,33 and 37* is/are rejected.

7)☒ Claim(s) *34-36 and 38-40* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/12/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group III, claims 32-37, in the reply filed on 6/22/2007 is acknowledged.

Claims 1-31 are cancelled.

Claims 38-40 are added.

Claims 32-40 are under examination.

Deposit

H425 antibody

With respect to claims 34-36, 38-40, it is apparent that the H425 antibody is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the cell line / hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

NOTE THE CURRENT ATCC DEPOSITORY ADDRESS

American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209

Applicant is reminded that the following and should amend the specification accordingly. The current address of the ATCC is as follows:
American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 32-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Bar-Or (US 20040175754).

Bar-Or et al. teach an isolated anti-dog (canid) albumin antibody (See Section 0087). Bar-Or et al. teach that such antibody can be either polyclonal or monoclonal (See Section 0046). The antibody can be used to detect albumin in a body fluid, e.g. urine, where the antibody has greater avidity (i.e. strength of binding) with albumin in the sample compared to other non-target proteins or other component in the sample. Supra.

4. Claims 32-33, 37 are rejected under 35 U.S.C. 102(e) as being anticipated by McDonald et al. (US 20030022262).

The applied reference has a common assignee Heska Corporation with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

McDonald et al. teach an isolated monoclonal antibody that specifically binds albumin from felid or canid (Col. 2, line 58-67). The antibody can be used to detect albumin in a body fluid, e.g. urine, where the antibody has greater avidity (i.e. strength of binding) with albumin in the sample compared to other non-target proteins or other component in the sample. Supra.

With respect to claim 37, McDonald et al. teach a kit containing the isolated antibody specific for canine or feline albumin (Col. 2, line 40-55), where the detection range for the albumin is from 10 μg/ml to 300 μg/ml (See Abstract).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 32-33 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohman et al. (US 4163778) in view of Forrest et al. (US 4659678).

Ohman et al. teach purifying antiserum (i.e. polyclonal antibody) that selectively binds to albumin from felid (Col. 5, line 25-32), where the antibody has greater avidity (i.e. strength of binding) with albumin in the sample compared to other non-target proteins or other component in the sample. Supra. However, Ohman et al. do not explicitly teach using monoclonal antibody.

Forrest et al. teach that monoclonal antibody provides more advantages in sensitivity and efficiency than polyclonal antibody in detecting analyte in a sample (Col. 2, line 1-10).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Ohman et al. to use monoclonal antibody specific for albumin from felid or canid in order to achieve better detection results with respect to specificity and efficiency.

With respect to claim 37, although the detection range is not explicitly disclosed, nevertheless it would have been obvious to one having ordinary skill in the art at the time the invention was made to achieve the optimal workable range since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

8. Claims 32-33 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Syme et al. (Proceedings 18th ACVIM Seattle WA, May 25-28, 2000 Abstract; Applicant submitted IDS on 1/12/2006) in view of Forrest et al. (US 4659678).

Syme et al. teach purifying antiserum (i.e. polyclonal antibody) that selectively binds to albumin from felid in an ELISA assay (see Abstract), where the antibody has greater avidity (i.e. strength of binding) with albumin in the sample compared to other non-target proteins or other component in the sample. Supra. However, Syme et al. do not explicitly teach using monoclonal antibody.

Forrest et al. teach that monoclonal antibody provides more advantages in sensitivity and efficiency than polyclonal antibody in detecting analyte in a sample (Col. 2, line 1-10).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Syme et al. to use monoclonal antibody specific for albumin from felid in order to achieve better detection results with respect to specificity and efficiency.

With respect to claim 37, although the detection range is not explicitly disclosed, nevertheless it would have been obvious to one having ordinary skill in the art at the time the invention was made to achieve the optimal workable range since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Allowable Subject Matter

9. Claims 34-36 and 38-40 are objected to as being dependent upon a rejected base claim, but would be allowable if (1) submitting H425 Deposit document compliance with the Deposit Rule set forth by the Office, and rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jacob Cheu
Examiner
Art Unit 1641

August 10, 2007

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600